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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/762,594      | 06/22/2001  | Vassilios Papadopoulos |                     | 6687             |

909 7590 08/22/2002  
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EXAMINER

BUNNER, BRIDGET E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1647

DATE MAILED: 08/22/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/762,594

Applicant(s)

PAPADOPOULOS ET AL.

Examiner

Bridget E. Bunner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 September 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17 and 34-35, drawn to an isolated PBR-associated protein DNA fragment, a recombinant DNA construct, host cell, and a method for producing PAP peptide.

Group II, claim(s) 18-22, drawn to an isolated recombinant PAP polypeptide.

Group III, claim(s) 23, drawn to a method for detecting a PAP in a sample comprising contacting sample with antibodies which recognize PAP and detecting the presence or absence of a complex.

Group IV, claim(s) 24, drawn to a method for detecting a PBR-associated protein, said method comprising the two hybrid assay.

Group V, Group V, claim(s) 25, drawn to an antibody to a peptide having the amino acid sequence specified in SEQ ID NO: 6.

Group VI, claim(s) 25, drawn to an antibody to a peptide having the amino acid sequence specified in SEQ ID NO: 7.

Group VII, claim(s) 25, drawn to an antibody to a peptide having the amino acid sequence specified in SEQ ID NO: 8.

Group VIII, claim(s) 25, drawn to an antibody to a peptide having the amino acid sequence specified in SEQ ID NO: 9.

Group IX, claim(s) 26, drawn to an antibody to a peptide having the amino acid sequence specified in SEQ ID NO: 11.

Group X, claim(s) 27-28, drawn to a method for detecting agents or drugs which reduce or eliminate PAP activity.

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Group XI, claim(s) 29 and 31, drawn to an agent or drug capable of inhibiting PAP activity.

Group XII, claim(s) 30 and 32, drawn to an agent or drug capable of promoting PAP activity.

Group XIII, claim(s) 33, drawn to a method for detecting at least one PAP in a sample using the polymerase chain reaction.

Group XIV, claim(s) 36-39, drawn to a therapeutic method for the treatment or amelioration of disease comprising providing to an individual an effective amount of an agent or drug which reduces or eliminates PAP expression or function.

Group XV, claim(s) 40, drawn to a method for modulating PBR activity, function, or targeting in a cell comprising increasing or decreasing level of PAP in said cell.

2. The inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

This PCT rule defines special technical features as technical features that identify a contribution which each of the claimed inventions, considered as a whole, makes over prior art. Claims 1-4 and 8 are anticipated by prior art. Li et al. (Genbank Accession No. AF020338), teaches a DNA fragment of an isolated PBR-associated protein (PAP). Therefore, claims 1-4 and 8 lack a special technical feature and cannot share one with the other claims.

3. Restriction is also required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Groups 1-5, claim(s) 1-17, 27-28, and 34-35, in part, drawn to one of 5 DNA fragments (SEQ ID NOs: 1, 2, 3, 4, or 5) coding for a protein, a vector, and a cell transformed with the DNA. For example, if Group 2 is elected, the claims will be searched to the extent that they read on SEQ ID NO: 2.

Groups 6-9, claim(s) 18-22, in part, drawn to one of 4 PAP polypeptides (SEQ ID NOs: 7-10). For example, if Group 7 is elected, the claims will be searched to the extent that they read on SEQ ID NO: 8.

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4. The inventions listed as Groups 1-5 and 6-9 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claims 1-17, 27-28, and 34-35 broadly encompass the nucleic acid sequences of 5 different genes or fragments. The nucleic acid sequences of Groups 1-5 are different lengths, composed of different nucleic acids, and are structurally and functionally unrelated, each to each other. The nucleic acid sequence imparts structural and functional differences in each gene which affect properties such as expression levels, tissue specific expression patterns, mRNA half lives, cellular localization of the gene product, etc. Furthermore, each gene encodes a different protein product which is not sufficiently linked by structural or functional features. Accordingly, each of the 5 different nucleic acid sequences recited in claims 1-17, 27-28, and 34-35 are not so linked under PCT Rule 13.1 and are thus placed in 5 different inventive Groups numbered 1-5, respectively.

Claims 18-22 broadly encompasses the amino acid sequences of 4 different polypeptides. The amino acid sequences of Groups 6-9 are different lengths, composed of different amino acids, and are structurally and functionally unrelated, each to each other. Accordingly, each of the 4 different protein sequences recited in claims 18-22 are not so linked under PCT Rule 13.1 and are thus placed in 4 different inventive Groups numbered 6-9, respectively.

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

aa. PAP7

bb. PAP8

cc. PAP15

dd. PAP20

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

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the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The claims are deemed to correspond to the species listed above in the following manner:  
See claims 23, 33-35.

7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (aa) is the PAP7 polypeptide. This special technical feature is not shared by any of the other species.

**In order to be fully responsive, Applicant must select one from Groups I-XV, one from Groups 1-5, and one from Groups 6-9. Applicant is advised that neither 1-5 nor 6-9 are species election requirements; rather, each of 1-5 and 6-9 is a restriction requirement.**

**If Applicant selects Groups I, III, or XIII, one species from the type of PAP polypeptide must also be chosen to be considered fully responsive.**

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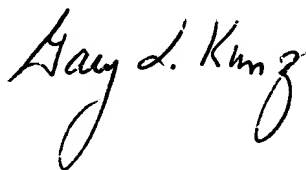
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

A handwritten signature in black ink that reads "Gary L. Kunz". The signature is written in a cursive style with a large, stylized "G" and "K".

BEB  
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August 20, 2002